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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,048	04/05/2007	Lotte Madsen	P69377US1	7119
69289	7590	04/01/2009		
COLOPLAST A/S Attention: Corporate Patents Holtedam 1 DK-3050 Humleback, DENMARK			EXAMINER LEWIS, KIM M	
			ART UNIT 3772	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,048	Applicant(s) MADSEN ET AL.	
	Examiner Kim M. Lewis	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 19-21, 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/18/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the invention of Group I, claims 1-18, 22 and 23 in the reply filed on 2/17/09 is acknowledged. The traversal is on the ground(s) that all claims 1-25 could be searched without series burden because they each pertain to a dressing product including a dressing sheet having an adhesive surface. This is not found persuasive because while each grouping identified by the examiner may contain a dressing product including a dressing sheet having an adhesive surface, Group II requires a cavity for accommodating the dressing sheet while Groups I, III and the unidentified Group containing the kit do not. Group III requires a thread, which is not required by Groups I and II and the unidentified Group containing the kit. And, the unidentified Group containing the kit requires a container and Groups I, II and III do not. Thus, to examiner all claims would require a serious burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

3. The information disclosure statement filed 12/18/06 has been received and made of record. Note the acknowledged PTO-1449 form or substitute therefor enclosed herewith.

Response to Amendment

4. The Preliminary Amendment filed 5/30/06 has been received and made of record. As requested, the specification and claims 4, 6 and 8-25 have been amended.
5. Claims 1-25 are pending in the instant application.

Claim Objections

6. Claims 14 and 23 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. More specifically, claims 14 and 23 depend on themselves.
7. While the metes and bounds of claim 1 are definite, in order to avoid confusion, applicant is advised to delete the term "means" from the claim since it is not necessary in the claim and since it is not linked to a means plus function recitation. Appropriate correction is required.

Claim Interpretation

8. The “means” recitation in claim 1 does not invoke 112, 6th paragraph.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As regards claim 4, "the area being uncovered" lacks proper antecedent basis.

As regards claims 14 and 23, the metes and bounds of the claims are not ascertainable since each claim is dependent upon itself.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-6, 8, 11, 13, 17 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,928,680 (Sandbank”).

As regards claim 1, Sandband discloses a dressing that anticipates Applicants' invention. More specifically, Sandband discloses a dressing product comprising a

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dressings sheet (thin film 2), one first surface of which is provided with an adhesive (3), whereby said first surface defines an adhering surface for attaching the dressings sheet to an anatomical surface of a living being; a carrier system (applicator 4) defining a gripping section for handling of the carrier system by human fingers, the carrier system providing a support for the dressings sheet and at least a part of the carrier system (5 or 11) is attached to the dressings sheet by means of said adhesive; the dressings sheet being releasably connected to or contained in the carrier system, so that the carrier system can be separated from the dressings sheet during application thereof, wherein the carrier system comprises a supporting section (5 or 11) and a protective sheet (5), said supporting section and protective sheet being adjoined along a curved or linear line (positioned near 7), wherein the adhering surface of the dressings sheet defines an overlapping region in which the sheet (5) adheres to the supporting section, and a non-overlapping region in which the sheet does not adhere to the supporting section.

As regards claim 2, Sandband discloses the dressings product according to claim 1, wherein the supporting section and the protective sheet are adjoined along a fold line (note protective sheet 5, which has a fold line 7 and which has an overlapping region adhered to the sheet and a non-overlapping region not adhered to the sheet).

As regards claim 3, Sandband discloses the dressings product according to claim 1 wherein the supporting section and the protective sheet are adjoined along an edge portion (the edge portion is defined by the fold).

Re. claims 4 and 5, note the slit that extends adjacent hinge (7).

As regards claim 6, as can be seen from Fig. 1, the carrier system defines an opening between hinge (7) and tab (12) which allows access to the dressing sheet while the dressing sheet is still connected to the carrier system.

Re. claim 8, as can be seen in Figs. 1-3 of Sandband, the gripping section defined by (6) extends substantially parallel to the plane defined by the dressing sheet and inherently has a bending stiffness which is sufficient to control application of the dressing sheet since it is involved in the application of the dressing sheet.

As regards claim 11, during use of the adhesive dressing of Sandband, the line that exists between fold (7) and member (11) is separated when tension is applied to the carrier system in the region of the line.

As regards claim 13, note col. 5, lines 45-46 of Sandband.

Re. claim 17, note col. 4, lines 31-46, which discloses the backing layer is constructed from polyurethane film.

Re. claim 22, the method is inherently practiced during application of the adhesive dressing to the user.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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17. Claims 7, 9, 10, 12, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sandband.

As to claim 7, note the rejection of claim 6 above. In further regards to claim 7, the opening is not provided centrally over the dressing sheet. However, the examiner contends that placement of the opening off center, as is done in Sandband, would perform equally as well as central placement of the opening. Thus, the location of the opening does not patentably distinguish applicant's invention and is considered a mere design choice.

As regards claims 9, 10 and 16, Sandband fails to disclose the claimed dimensions of the dressing sheet, gripping section, and the adhesive layer. However, it has been held that a change in size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F. 2d 459, 'SPQ 237 (CCPA 1955). Thus, it would have been obvious to one having ordinary skill in the art to modify the dimensions of the dressing sheet, gripping section and/or adhesive layer as needed depending upon the intended use of the dressing product. Sandband also fails to disclose the claimed vapor permeability range of the dressing (note col. 4, lines 54-59). However, it has been held that where the general conditions of a claimed are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220, F.2d 454 , 456, 105 USPQ 233, 235 (CCPA 1955). Thus it would have been obvious to one having ordinary skill in the art, through routine experimentation, to determine the optimum or workable ranges of the vapor permeability of the dressing.

As regards claim 12, Sandband fails to disclose that the protective sheet is integral with the supporting section of the carrier system and wherein the carrier system defines a weakend breaking line at the transition between the supporting section and the protective sheet. The examiner contends that such carrier systems are well known in the adhesive dressing art, note for example, US. Patent No. 5,998,694. Thus, it would have been *prima facie* obvious to one having ordinary skill in the art to substitute one carrier system for another carrier system as an obvious exchange of parts, which perform the same function.

18. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sandband in view of U. S. Patent No. 6,303,700 ("Chen")

As regards claims 15 and 18, Sandband fails to teach hydrocolloid particles in the adhesive layer, as well as a medicament in the adhesive. Chen, however, teaches that it is conventional in the art to provide hydrocolloid particles in an adhesive for use on a wound in order to absorb wound exudate. Further taught is the use of medicaments in the adhesive for the purpose of treating the skin or wound. Thus, it would have been obvious to one having ordinary skill in the art to substitute the adhesive of Sandband for the adhesive of Chen which includes hydrocolloid particles and/or medicaments, in order to allow the adhesive wound dressing to absorb wound exudate and to treat the wound.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-

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4796. The examiner can normally be reached on Wednesday to Friday, from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kim M. Lewis/
Primary Examiner
Art Unit 3772

kml
March 29, 2009